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Keane, E., Bharghava, E., Claerhout, M. et al. (2024) New frontiers in pediatric cochlear implant surgery – a single center experience with the 3-dimensional exoscope. The Journal of International Advanced Otology, 20 (5). pp. 379-382. ISSN: 1308-7649

https://doi.org/10.5152/iao.2024.231240

The Journal of International Advanced Otology

J Int Adv Otol 2024; 20(5): 379-382 • DOI: 10.5152/iao.2024.231240

Original Article

New Frontiers in Pediatric Cochlear Implant Surgery – A Single Center Experience with the 3-Dimensional Exoscope

Emma Keane, Eishaan Bharghava, Michiel Claerhout, Benjamin Miller, Irumee Pai, Nikul Amin, Dan Jiang

Evelina Children's Health, London, UK

ORCID iDs of the authors: E.K. 0000-0003-2192-5558, E.B. 0000-0003-2619-8484, M.C. 0000-0002-5677-6110, B.M. 0000-0001-5368-2605, I.P. 0000-0003-3023-4572, N.A. 0000-0001-9579-8454, D.J. 0000-0003-1490-6658.

Cite this article as: Keane E, Bharghava E, Claerhout M, et al. New frontiers in pediatric cochlear implant surgery – A single center experience with the 3-dimensional exoscope. *J Int Adv Otol.* 2024;20(5):379-382.

BACKGROUND: Since its introduction by Wullstein, the binocular surgical microscope has remained the gold standard of visualization in the field of otology. However, in the last decade, new technology became available in the form of the three-dimensional (3D) exoscope. In this article, we describe our experience thus far in pediatric cochlear implantation with the 3D exoscope.

METHODS: This article is about prospective descriptive study of all exoscopic cochlear implant (CI) cases in a quaternary pediatric CI center performed with the Vitom® 3D system. All pediatric patients (age <18) were included without exclusion criteria, and our experience and conversion to microscope rates are reported.

RESULTS: Since the introduction of the exoscope to our unit, we have successfully performed 68 cases, of which 53 were bilateral cochlear implantations. The age of the patient varied between 10 months and 209 months (average: 64 months; median 46.5 months). There were a total of 121 implantations (96 primary implantations, 24 revision implantations). There were 2 conversions to the traditional microscopic technique.

CONCLUSION: The exoscope provides a 3D high-definition (4K) images in CI surgery. There is limited data regarding its use, and we identified a number of advantages including efficiency, occupational health, theater utilization, surgical training, and safety. Although there are areas still for improvement, such as loss of signal-to-noise ratio at higher magnification, manual focus, and lack of electromagnetic articulation in the holding arm, we have found it to be a useful addition to the surgical armamentarium within pediatric cochlear implantation.

KEYWORDS: Children with cochlear implants, cochlear implantation, ear surgery

INTRODUCTION

Since its introduction by Wullstein, the binocular surgical microscope has remained the gold standard of visualization in the field of otology. Access to the middle ear is notoriously challenging and a clear, magnified image is required at all times.[1,2] Over the years, there have been major improvements with surgical microscopes in terms of size, maneuverability, focusing, and flexibility, but further progress and innovation are still possible.[1]

Some alternatives have been employed to mitigate these drawbacks and improve visualization in more challenging areas, with endoscopic ear surgery being adopted in many units. However, this technique has been under some scrutiny due to its single-handed nature, so-called "fisheye" effect, and perceived lack of depth perception.[3] In relation to cochlear implantation, a systematic review has concluded the paucity of relevant studies signifies its use as the primary modality cannot be supported.[4] Also, as the basal turn of the cochlea follows a more posterior angle than that of the ear canal, the trajectory of the classical posterior tympanotomy remains the most suitable pathway for access.[5]

More promising technology has become available almost a decade ago,[6] the 3D exoscope. This is a hybrid optical system with a camera mounted outside the surgical field. At the time of writing this article, there are 4 such systems available: the Vitom® (Karl Storz, Tuttlingen, Germany), the ORBEYE (Olympus, Tokyo, Japan), Kinevo® (Carl Zeiss Meditec AG, Oberkochen, Germany), and the

A poster version of this paper was presented at the British Cochlear Implant Group Meeting, 13-14 April 2023, Cambridge, UK
Corresponding author: Emma Keane, e-mail: emmakeane@rcsi.ie
Received: November 30, 2023 • **Revision Requested:** April 20, 2024 • **Last Revision Received:** July 2, 2024 • **Accepted:** July 24, 2024 • **Publication Date:** September 26, 2024
Available online at www.advancedotology.org

Modus V™ (Synaptive Medical, Toronto, Canada)—the latter being described by the company as a microscope.

In this article, we describe our experience thus far in pediatric cochlear implantation with the Vitom® 3D system. To our knowledge, this is the largest case series describing this technique in the pediatric population and includes cases of unilateral, bilateral simultaneous, and explant and reimplant procedures.

METHODS

Study Design and Settings

This article is about prospective descriptive study of all exoscopic cochlear implant (CI) cases in a quaternary pediatric CI center. All pediatric patients were included without exclusion criteria, and our experience and conversion to a microscope rates are reported. This retrospective descriptive study was registered and approved as a service evaluation with Guy's and St Thomas' NHS Foundation Trust (Audit Number: 15349). Written informed consent was obtained from each individual patient's parent/legal guardian.

Equipment

The Vitom® 3D system comprises: 3D exoscope, holding arm (Versacrane™), controller for zoom, focus, and view of field (Pilot), light source (Power Led 300), camera controller (S Connect), a link module (S D3), and a 26-inch high-definition (4K) 3D monitor. The image on the monitor is viewed with three-dimensional (3D) polarization glasses (Figure 1).

Training

Prior to introducing the exoscope to clinical practice, extensive training on cadaveric specimens was provided to senior surgeons over a 3-day temporal bone dissection course. The exoscope was in continuous use over this period, with multiple simulated CI procedures and more extensive dissections performed.

We found no major differences in the surgical technique required, and after familiarizing oneself with setup and camera manipulation, transitioning to the use of the exoscope was a seamless experience.

Figure 1. The 3D Exoscope setup and equipment, the Versacrane, 4K monitor, and S Connect are depicted. The surgeon wears 3D polarization glasses. *Source:* Karl Storz.

Prior to formal acquisition, the equipment underwent a 1-month trial with one-to-one theater staff training on-site, and representatives were present for the first 5 cases.

Operating Theater Setup

The positions of the surgeon, scrub nurse, anesthetist, and equipment are shown. (Figure 2). The exoscope is covered with a sterile drape so that the operating surgeon can adjust the angle of visualization as required. The Pilot joystick controller is mounted on the operating table next to the surgeon and is used to control magnification, image orientation, focus, and camera functions. Other equipment that would typically be used in conjunction, such as the drills and suction, was utilized in a standard manner.

RESULTS

At the time of publication, there are 2 surgeons routinely utilizing the exoscope for CI surgery. Since the introduction of the exoscope to our unit, we have successfully performed 115 CI surgeries, of which 43 were primary bilateral cochlear implantations. The age of the patients ranged between 10 months and 209 months (average: 64 months; median: 46.5 months). There were 16 explant and reimplantation cases. We also did one explantation of a CI without reimplantation. The procedure type is summarized in Table 1. This is currently the largest known case series in the literature concerning exoscopic pediatric cochlear implantation.

There were 2 conversions to the traditional microscopic technique—in one instance, the light source had been damaged and the image was too dark. This was resolved by replacing the light source. In the second instance, aberrant facial nerve anatomy prevented adequate visualization of the relevant structures, necessitating the use of the microscope. This may not only reflect the learning curve but also the complex nature of the cases seen in our unit.

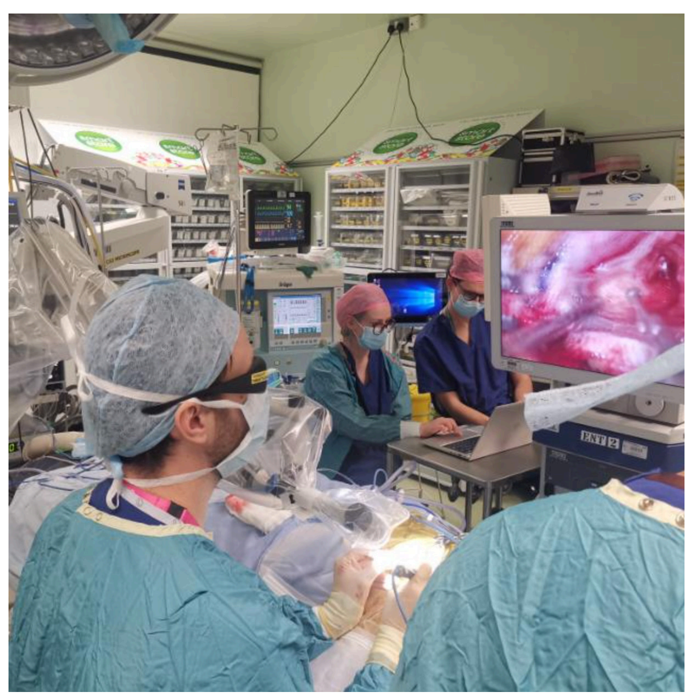

Figure 2. Real-time example of operating room setup, posterior tympanotomy commenced. The Versacrane, 4K monitor, and S Connect are depicted. The surgeon wears 3D polarization glasses. *Source*: Personal library.

Table 1. Procedure Type and Frequency

Procedure Type	Unilateral	Bilateral	Total
Primary implant	4	43	90
Explant and reimplant	8	8	24
Explant	1	0	1

Operating Time

A comparison of operating time was made between the first 12 introductory bilateral simultaneous primary cochlear implantations and the most recent 12 such cases by the senior author. A decrease of 22 minutes was seen, although this failed to achieve statistical significance (two-tailed paired *t*-test: $P = .298$).

When we compare the time of the last 5 exoscopic bilateral simultaneous primary cochlear implantations to the time of 18 similar microscopic cases, the operating time is decreased by 29 minutes. This again was not found to be statistically significant (two-tailed paired *t*-test: $P = .096$). Additionally, the first 5 exoscope cases saw a time decrease of 7 minutes compared to the reference microscope cases.

With this in mind, there does not seem to be a significant loss or gain of time when comparing the exoscope to the microscope, even if one is highly experienced with the microscope. However, the post hoc power analysis revealed that our study is in fact underpowered to demonstrate smaller differences in operating times ($Dz < 0.4$)

Complications and Conversion to Microscopic Technique

No complications were noted during this time period. All patients were discharged well on the day of surgery/post-operative day 1. At 1-week review, there were no surgical wound infections, and the patients were carried forward into their audiological rehabilitation program as planned.

There were 2 conversions to the traditional microscopic technique—in one instance, the light source had been damaged, and the image was too dark. This was resolved by replacing the light source. In the second instance, aberrant facial nerve anatomy prevented adequate visualization of the relevant structures, necessitating the use of the microscope. This may reflect not only the learning curve but also the complex nature of the cases seen in our unit. This second conversion occurred at the outset of the exoscope being introduced, at which point recourse to a more familiar technique for purposes of fluent navigation in challenging anatomy was deemed appropriate, and no conversions for this reason have been necessary since. The microscope is kept in close proximity to facilitate such conversions.

DISCUSSION

The exoscope provides 3D high-definition (4K) images in CI surgery (Figure 3). There are limited data regarding its use, and we identified a number of advantages and areas for future improvement during our appraisal.

Surgeon's Experience

The system is easy to set up and compatible with existing theater equipment. The transition between the exoscope and microscope is straightforward, owing to a combination of the compact design and maneuverability of the exoscope and little competition for space at the head end of the operating table. There was no need to move heavy equipment in and out of the way or disrupt the physical setup. The same monitor and stack system is used for both. This is in keeping with similarly positive experiences described in the literature.[7-9]

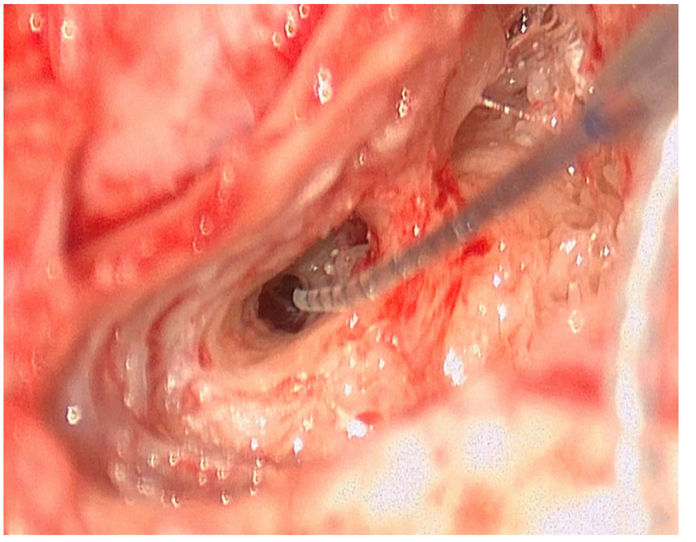

Figure 3. Cochlear implant electrode insertion as seen on the 3D monitor. A cortical mastoidectomy and posterior tympanotomy have been performed, with the electrode seen placed via the round window (*Source*: Personal library).

In CI surgery, the additional advantage of the compact design improved access to the surgical field whilst strictly ensuring sterility, especially during device placement and insertion.[2,10] The considerably smaller footprint of the Vitom® 3D system facilitated a safer working environment with a more efficient flow within the operating theater. The improved portability contributed to more flexible utilization of the wider theater facilities by enabling smaller procedures that would still require a microscope to take place safely in an anesthetic room or a procedure room. Similar to the report by Sassou et al,[11] the greater portability was also found to be advantageous during transfer between different theaters and hospital buildings, with lower risks of damage to the instrument and manual handling concerns for staff.

Training and Education

Microscopic surgery can be a challenging experience for both the trainer and the trainee, due at least in part to the differences between the side arm and the main eyepiece in terms of visualization of the operative field and depth perception. The 3D exoscope offered everyone in the theater the same stereoscopic visualization, allowing the trainee to follow the surgical steps more clearly and giving the trainer more confidence to provide guidance safely. The system is capable of recording 3D videos, which may become an increasingly important aspect in training and education.[8,12]

The Exoscope During the Coronavirus Disease 2019 Pandemic

In these unprecedented times of the coronavirus disease-2019 (COVID-19) pandemic, with otolaryngologists significantly predisposed to contracting the virus, wearing enhanced personal protective equipment has become mandatory. Goggles and face shields can dramatically increase the distance of the eye to the microscope eye piece, with the surgeon's field of vision often being reduced by more than 50%.[13] Analysis of the exoscope in the COVID-19 era proposed that it provides an ergonomic solution to this situation, as the 3D glasses protect the eyes from aerosol while providing a clear image. In addition, the ability to access the same view of the surgical field as the operating surgeon by all theater personnel allows for improved engagement and more effective communication within the team.[2,14]

Limitations

Although our experience with the Vitom® 3D system has been positive overall, a number of areas for improvement have also been identified.

Firstly, there was some loss of signal-to-noise ratio at higher magnifications due to the digital, as opposed to optical, zoom. In addition, the maximum level of magnification achievable in our current setup with a 26-inch screen was lower than that with a microscope. The level of highest magnification depends on the screen size of the external monitor as well as the distance between the exoscope and the surgical field, something that will need to be considered in conjunction with the anticipated use of the exoscope.

Whilst we attribute our second microscope conversion to the need for fluency in challenging anatomy, it remains plausible that scenarios may arise where magnification and resolution requirements necessitate conversion to a microscope, and we strongly recommend the continued availability of the microscope when utilizing the exoscope. An autofocus system would also be useful when changing magnification.

Secondly, the lack of electromagnetic articulation in the holding arm necessitates somewhat crude manual adjustments when repositioning the exoscope, which feels cumbersome compared to a modern microscope. The introduction of the robotic ARTip™ Cruise (Karl Storz, Tuttlingen, Germany) system may be useful in reducing interruptions to the flow of surgery.

It is important to mention the capital outlay and the cost of running and maintenance of the equipment, which, at an estimated USD $250 000-325 000[15] is much higher than the standard operating microscope. With finite resources, it can be difficult to make a successful bid for funding. Nonetheless, the cost can be spread by making the equipment available to other specialties within the Trust. In Guy's and St Thomas', the exoscope is also utilized by the plastic surgery team in cleft palate and by the subspeciality pediatric ENT airway service in diagnostic microlaryngoscopy. The fact that the system is already compatible with the existing equipment and can be utilized across different subspecialties made it a cost-effective solution overall.

CONCLUSION

In our experience, the 3D VITOM® confers several distinct advantages over a standard microscope, including efficiency, occupational health, theater utilization, surgical training, and safety. Although there are still areas for improvement, we have found it to be a useful addition to the surgical armamentarium within pediatric cochlear implantation.

Ethics Committee Approval: This retrospective descriptive study was registered and approved as a service evaluation with Guy's and St Thomas' NHS Foundation Trust. (Approval no.: 15349, Date: 20/11/2023).

Informed Consent: Written informed consent was was obtained from each individual patient's parent/legal guardian.

Peer-Review: Externally peer-reviewed.

Author Contributions: Concept – E.K., E.B., I.P., N.A., D.J.; Design – E.K., B.M.; Supervision – I.P., N.A., D.J.; Data Collection and/or Processing – E.K., B.M., E.B., M.C., Literature Review – E.K., E.B., B.M.; Writing – E.K., E.B., B.M., M.C.; Critical Review – D.J.

Declaration of Interests: The authors have no conflicts of interest to declare.

Funding: The authors declare that this study received no financial support.

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